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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: Comments on peer review guidance

Dear Ms. Schwab,

The Ornithological Council's comments on the proposed peer review guidance are attached. As I have not yet scanned our letterhead, I have provided my contact information at the end of the letter, and also provide it below, for your convenience.

I will mail a hard copy later today, but of course wanted to be sure that the comments were received by your office before the deadline.

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"Providing Scientific Information about Birds"

- OMB-peer-review.doc

11 December 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
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Room 10201
Washington, D.C. 20503

Delivered by e-mail to OMB_peer_review@omb.eop.gov

Dear Dr. Schwab,

The Ornithological Council appreciates the opportunity to submit comments on the Proposed Bulletin on Peer Review and Information Quality. A consortium of scientific ornithological societies with a cumulative membership of approximately 6,500 scientists, the Ornithological Council addresses government policies that affect the manner in which scientific research is conducted or that have an impact on the way that scientific information is used in decision-making.

We agree unequivocally with the Office of Management and Budget and the Office of Science and Technology Policy that objective peer review is a critical element in ensuring the reliability of scientific analyses. We also agree with the premise that “independent peer review is especially important for information that is relevant to regulatory policies.” The Office of Management and Budget is to be lauded for its efforts to realize – and perhaps optimize – the “benefits of meaningful peer review of the most important science disseminated by the Federal Government regarding regulatory topics.”

However, several of the specific elements proposed by the OMB may actually have just the opposite effect or may preclude the use of scientific information in decision-making. It is because peer review is so critically important that we are concerned about the potential impact of some of the specifics of this guidance. The value of peer review could actually be diminished if agencies follow some of these recommendations.

We have identified several specific areas of concern.

Cost of compliance and implications for science and the use of science in decision-making

Despite the title, the text of the proposed Bulletin makes it clear that compliance is mandatory. For instance, the text states that “The Bulletin also recognizes that waivers of these requirements may be required in some circumstances, such as when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical.” Waivers are to be granted only by the Administrator of the Office of Information and Regulatory Affairs. Agencies therefore must comply absent a waiver.

Agency budgets are already stretched thin. To comply with this Guidance (as well as the data quality guidelines), they must necessarily devote resources such as staff time, travel expenses, printing expenses, and the like. Yet no additional resources have been appropriated for compliance. This is particularly true with regard to the formation of federal advisory committees (discussed more fully below). Agencies may be required to divert funds from programs that fulfill agency missions (such as scientific research) in order to comply. Lack of adequate funding alone may make it impracticable to comply fully.

The Office of Management and Budget does not make a compelling case that this expense is warranted. The introductory matter discusses a report from the Inspector General of the Environmental Protection Agency, but offers no evidence that the shortcomings in peer review practice are common. The EPA response to the Inspector General's report acknowledged that the peer-review policies at the agency were in flux over the decade during which the policies in question were produced and implemented. The EPA asserted that since newer policies were implemented, the peer-review practices at the agency had improved, and noted that the Inspector General hadn't assessed whether the agency's peer-review practices had improved over time.

The Office of Management and Budget might want to consider the benefit that would result from imposition of this Guidance. If there is no widespread problem with peer review practices among the federal agencies that would be affected by this policy, then it would seem that there might be little benefit to be gained. If the problems are isolated to one or more specific agencies, the imposition of the costs of this guidance to all agencies might not be warranted.

The Office of Management and Budget might want to consider undertaking an analysis of the cost of compliance with this Guidance (as well as compliance with the data quality guidelines) for the purposes of (a) determining when an agency's financial status makes compliance impracticable and (b) formulating Presidential budget requests to Congress that include additional funds for compliance with these directives.

We note that the Guidance requires an annual report. We suggest that the Guidance require that agencies report on the cost of compliance with the Guidance, including compliance with the reporting requirement.

Selection of peer reviewers

We agree fully that potential conflicts and other sources of bias should be disclosed. However, other aspects of the Guidance with regard to the selection of peer reviewers could function to dissuade the agency from including highly-qualified scientists from participation in the peer review process.

Specifically:

a) The agency is instructed to consider whether the scientist has, in recent years, advocated a position on the specific matter at issue.

The peer review panel should be reviewing only the science and the application of science to a given issue, not the issue under consideration by the agency. This standard would suggest that anyone with a publicly-stated view on the policy matter under consideration by the agency might be disqualified from serving on a peer review panel, regardless of the scientist's expertise on the scientific matters. If a scientist has taken such strong and extreme views on an issue for reasons unrelated to science, that scientist might not be suitable to serve as a peer reviewer. However, scientists regularly take stances on the scientific matters that may be pertinent to the issue at hand. It is common for scientists to debate scientific issues in journals, scientific meetings, and in the meetings of panelists convened by the National Academies of Science, the Environmental Protection Agency's Scientific Advisory Board, and the National Institute of Health's consensus development conferences. Indeed, the purpose of these official meetings is often to air and discuss divergent views on scientific issues. To discourage agencies from selecting scientists who have advocated positions on the scientific aspects of the specific matter at issue could serve to eliminate from the panels those with the greatest expertise.

In addition, this standard could actually introduce, rather than eliminate, bias. It may be better to include someone whose views are known than to select someone who has hidden his or her views on the issue, or not spoken publicly on the subject. It is very difficult to find peer reviewers who have no views on a given issue. In fact, it may be impossible to determine an individual's views, because if that individual wishes to serve on a panel so as to influence the outcome, that individual is unlikely to admit to a bias.

Another troubling implication of this standard is the potential impact on scientists and scientific discourse. A standard that selects for those who do not share their views could discourage open scientific discourse. It also has the potential to chill free speech by scientists.

b) The agency is instructed to consider whether the scientist is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university)

All conflicts and potential conflicts – financial or otherwise – should be disclosed. However, those who successfully compete for funding from an agency may be those who are doing the best work in that field. It would be contrary to OMB's purpose to preclude these individuals from serving on peer review panels, but this may be the unintended result of this instruction. The OMB guidance does not give the agency guidance in how to use this information. The instruction implies that funding leads to bias. Does OMB intend for the agency to exclude those who have been funded by the agency? What other measures does the OMB intend for the agency to take to determine if, in fact, a scientist receiving funding is biased? And, in fact, someone who was denied funding may well be biased for that reason.

A more troubling implication of this standard is the differential exclusion of those who receive funding from federal agencies as opposed to those who receive funding from

private industries that will likely be affected by the outcome of the regulations to which the science pertains. While industry-employed scientists may not be inherently biased, there is no reason to believe that industry-employed scientists are less subject to bias emanating from the funding source than are other scientists. By suggesting that scientists who are funded by an agency may have conflicts, without recognizing that those who do not receive agency funding (i.e., industry-employed scientists) may also be biased, there is a real possibility that the panels will be populated primarily by industry-employed scientists. This could introduce an unintended bias to the peer review process, contrary to the intent of the OMB Guidance.

c) The agency is instructed to consider whether the scientist has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same *specific* matter in recent years.

The scientist who has conducted multiple peer reviews for the agency, or multiple reviews on the same specific matter, could very well have served repeatedly because he or she is recognized by peers to have great expertise on the matter. Further, depending on the breadth and complexity of the scientific issue and the scientific disciplines that are relevant to that issue, the pool of appropriate reviewers may be very small. It may not be able to find someone who has not reviewed the same matter many times.

d) The agency is instructed that, "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel."

This seemingly common-sense instruction could in fact be very problematic, if not completely unworkable. If the bias of reviewer A is only perceived, then does balance require another reviewer whose bias is contrary to that of reviewer B, but is only perceived. If B's bias is real, rather than perceived, then there is no actual balance. If both have real biases, but one has stronger biases than the other, how is the balance to be adjusted. Assuming that the biases are balanced, must the two reviewers be equally qualified in order to achieve true balance?

The policy makes no exemption for statutory standards that may prescribe a different standard

Some statutes, such as the Endangered Species Act, require the "best scientific information available."

Section 4 (b) - the listings section -reads " (1)(A) The Secretary shall make determinations required by subsection (a)(1) solely on the basis of the *best scientific and commercial data available* to him after conducting a review of the status of the species and after taking into account those efforts, if any, being made by any State or foreign nation, or any political subdivision of a State or foreign nation, to protect such species, whether by predator control, protection of habitat and food supply, or other conservation practices, within any area under its jurisdiction, or on the high seas."

Sometimes (not often) the best scientific information available may not be peer-reviewed. In that case, the OMB Guidelines could force the Secretary of the Interior to

make decisions without consideration of the scientific information that is mandated by the statute.

FACA will delay and may preclude peer review

The proposed guidelines recommend, but do not mandate, that an agency assess the treatment of peer review panels under the Federal Advisory Committee Act (FACA). While FACA has definite benefits, it may not be suitable for peer-review panels, if for no reason other than impracticality. Establishing a federal advisory committee can and usually does take a year or more. Agencies must have enough staff to manage these committees and to comply with record-keeping requirements, public notice requirements, and financial management requirements and typically need funding for travel costs for committee members.

It should also be noted that there is a cap on the number of Federal Advisory Committees that an agency can establish. If an agency has reached that cap, and cannot obtain a waiver of the cap, then the agency must choose between adherence to the OMB recommendation or delaying the peer review process, and, in consequence, the decision-making process. The net result, then, of this recommendation may be that peer review processes may be delayed or curtailed.

Charge to reviewers and opportunity for public comment

If the purpose of this Guidance is to assure that peer review is unbiased and of high quality, then the provision for public comment is puzzling. Will the commenters be screened for qualification, bias, and conflict of interest? If not, then these comments could introduce the biases and conflicts that this Guidance seeks to eliminate. Further, it is curious that the Guidance does not limit the nature of the public comment to scientific information. A peer review panel should consider only the matters in which its members have expertise. The peer review panel should not consider information unless it pertains directly to the quality or implication of the scientific matters under review.

Application of outcome of peer review to decision-making

The guidance fails to discuss how the agency is to make use of a peer review process that does not result in a consensus about the science. Peer review is a process, not a result. The goal is to assess the credibility of the science but not necessarily to reach agreement on the implications of the science to the management issue. For instance, the NIH Consensus Development Conference expressly allows for the expression of minority views. Governments cannot wait to act until there is complete scientific certainty. Agencies should be given guidance that the failure of a peer review panel to reach consensus does not preclude agency decision-making. It is the intent of the OMB, according to a Washington Post article citing OIRA chief John Graham (30 August 2003), that this guidance, “their rules more competent and credible and reduce their vulnerability to political and legal attack.” In fact, the opposite effect is also likely: opponents of a regulation could cite as the basis for an attack the failure of the peer review panel to reach consensus.

Independent review of the peer review process

To fully achieve the goals of this Guidance, the agency peer review processes should be reviewed by panels of independent experts in peer review systems. Both OIRA and OSTP are staffed by administration employees and political appointees. Some may have expertise in peer review systems, but that does not eliminate the possibility of bias. In fact, OIRA exercises review of regulations, so OIRA staff who review peer review systems may have also been called upon to express a position on specific regulations. It would seem critical that to best serve the goals of this Guidance, the reviews of agency peer review processes should conform to this Guidance.

We urge the Office of Management and Budget to consider engaging in consultation with the scientific community before finalizing and implementing this Guidance, for the purpose of addressing concerns of the nature we have raised and for the purpose of assuring that the goals of the Guidance are achieved. The scientific community has demonstrated its willingness to assist the administration in assuring that the administration's legitimate and laudable interest in assuring that the science underlying government decisions is sound. With its considerable expertise and experience with peer review, it is likely that such consultation could result in a Guidance that both assures adequate peer review while averting negative impacts on the application of science to agency decision-making processes and on the agencies' abilities to fulfill their missions.

We thank the Office of Management and Budget for considering our concerns.

Sincerely,

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